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| 09/724,755      | 11/28/2000  | Hans-Michael Wenz    | 7414.0020-03        | 8421             |

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/17

**Office Action Summary****Application No.**

09/724,755

**Applicant(s)**

WENZ, HANS-MICHAEL

**Examiner**

Jeffrey Fredman

**Art Unit**

1637

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 131-134 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 131-134 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status**

Claims 131-134 are pending.

Claims 131-134 are rejected.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

### ***Claim Interpretation***

1. In claims 131-134, the term "amplification product" is read as a nucleic acid that is not chemically synthesized. Since DNA or RNA can be amplified, in either single stranded (as in asymmetric PCR) or double stranded form (as in regular PCR or in mini or maxi preps from E. coli, for example), any non chemically synthesized DNA will meet the requirement of being an "amplification product."
2. In claims 131-134, the term "addressable support specific portion" is interpreted as a nucleic acid that can bind a complementary nucleic acid probe. Any nucleic acid sequence whatsoever can meet this limitation since any nucleic acid sequence can hybridize to the complementary sequence by Watson-Crick base pairing.
3. In claims 131-134, the term "mobility modifier" is read (in context of the claim that requires at least two such modifiers) as requiring two nucleic acids that can bind to two different "amplification products" (as broadly defined above) which differ either in their length, or in the label that is attached to them. Applicant is correct that the limitation can be even broader than interpreted above. However, the above explanation is intended to indicate how the prior art cited below is applied.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 131-134 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedhoff et al (Anal. Biochem. (1993) 215:9-16).

Friedhoff teaches a composition comprising

(i) a plurality of different amplification products (see page 11, figure 1 and page 12, column 1, subheading "Polymerase Chain Reaction", where there are two different amplification products, with either a AT or GC basepair at the SNP site) which comprise;

(a) a first primer specific portion (see page 12, column 2, where both different amplification products are amplified using a common upstream primer),

(b) a second primer specific portion (see page 12, column 2, where both different amplification products are amplified using a common downstream primer)

(c) and an addressable support specific portion, between the primer specific portions that is different for each of the amplification products (see page 11, figure 1, where one amplification product has an AT basepair and the other a GC basepairs that is distinct)

and

(ii) at least two different mobility modifiers, (see figure 1 and page 12, where the two probes, the Fluorescein labeled and digoxigen labeled probes that bind to the addressable support specific portion represent two different sequence specific mobility modifiers) which further comprises:

(a) a tag complement for specifically binding the addressable support specific portion of one of the plurality of different amplification products (See figure 1 and page 12, where the two probes each bind to the proper amplified PCR products),

(b) a tail which imparts to each mobility modifier a distinct mobility relative to the other mobility modifiers (see figure 1 and page 12, where each of the probes has a different chemical label with a different molecular mass that would result in a different mobility, one of which is fluorescein, the other of which is digoxigenin)

With regard to claim 132, all of the addressable support specific portions are substantially the same length (see figure 1, and page 10 where each probe is 24 nucleotides in length),

With regard to claim 133, each of the mobility modifiers has a label, one of which is digoxigenin, the other of which is fluorescein (see page 10, column 2 and figure 1).

With regard to claim 134, the second primer specific portion is the same for each different amplification product (see figure 1 and page 12).

***Response to Arguments***

6. Applicant's arguments filed February 5, 2004 are moot in view of the new grounds of rejection.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman  
Primary Examiner  
Art Unit 1637